K053349 p/2

DEC 9 2005

Summary of Safety and Effectiveness
Hoffmann® II Rod to Wire Coupling

Proprietary Name:	Hoffmann® II Rod to Wire Coupling
Common Name:	External Fixation Frame Components
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT
For Information contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	December 1, 2005

Description:

This Special 510(k) submission is a line extension intended to add an alternate style of coupler to the Hoffmann® II External Fixation System.

Intended Use:

The modifications do not alter the intended use of the predicate system as cleared in the referenced premarket notifications. The subject and predicate devices are sterile and non-sterile external fixation frames intended to provide stabilization of open and/or unstable fractures. The indications for use for the Hoffmann® II Rod to Wire Coupling are provided below.

Indications for Use:

The Hoffmann® II Hybrid External Fixation System is intended to be used in conjunction with the Apex™ Half Pins of the Hoffmann® External Fixation System and Kirschner Wires of the Monticelli Spinelli™ External Fixation System, and may be used as a Hybrid External Fixation System with the components of the Hoffmann® II External Fixation System and the Monotube® TRIAX™ External Fixation System.

This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation.

Substantial Equivalence:

The subject Hoffmann® II Rod to Wire Coupling shares the same intended use, and basic design concepts as that of the currently available Hoffmann® II External Fixation System and Hoffmann® II Hybrid Frame System. Mechanical testing demonstrated comparable mechanical properties to the predicate components and is substantially equivalent to these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Francisco Haro
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K053349
Trade/Device Name: Hoffmann® II Rod to Wire Coupling
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: November 30, 2005
Received: December 2, 2005

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K053349

Device Name: Hoffmann® II Rod to Wire Coupling

Indications for Use:

The Hoffmann® II Hybrid External Fixation System is intended to be used in conjunction with the Apex™ Half Pins of the Hoffmann® External Fixation System and Kirschner Wires of the Monticelli Spinelli™ External Fixation System, and may be used as a Hybrid External Fixation System with the components of the Hoffmann® II External Fixation System and the Monotube® TRIAX™ External Fixation System.

This device is used to provide stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K053349